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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/618,424	07/18/2000	Yoichi Taya	49979	9451

21874 7590 08/26/2003

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EXAMINER
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PADMANABHAN, KARTIC

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 08/26/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.	Applicant(s)	
09/618,424	TAYA ET AL.	
Examiner	Art Unit	
Kartic Padmanabhan	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) Responsive to communication(s) filed on 10 August 2003.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) Claim(s) 16-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 16-24 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 21.
- 4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/10/03 has been entered.

### ***Information Disclosure Statement***

2. The information disclosure statement filed 7/17/03 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. Therefore, Japanese document 5-500007 has not been considered.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 16-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. In claim 16, the recitation of an antibody concentration greater than 0.01ug/ml is vague and indefinite because applicant has not recited an upper bound of concentration.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lill et al. (*Nature*, 1997).

Lill et al. teach that p300/CBP (which is considered to be an acetyltransferase) binds to p53 in the absence of viral oncoproteins. The reference also teaches that E1A disrupts binding of

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p300/CBP to p53 by binding to p300/CBP. The reference teaches the tagging of p53 with green fluorescent protein in a binding assay to show the binding of p300/CBP to p53. However, when E1A is cotransfected with GFP-P53 and epitope tagged p300, binding does not occur. The reference does not teach a kit, nor does it teach deacetylase.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to package the components of Lill et al. in a kit due to the long recognized ease and convenience conferred by such an arrangement. In addition, the various reagents used to carry out an assay are often packaged together in a kit, which a skilled artisan would have known. In addition, it would have been obvious to make deacetylase a component of the kit. Since the claimed method recites selecting a compound that is associated with an increase or decrease in the amount of acetylated peptide, one would have had a reasonable expectation of success in making deacetylase a component of the kit and using it to deacetylate acetylated peptide substrates.

10. Claims 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gu et al. (Cell, 1997).

Gu et al. teach that p53 is a substrate for p300 acetyltransferase. P53 was labeled by acetyl CoA, but labeling required the presence of both acetyl CoA and p300. The reference also teaches that bacterially produced p53 is inactive in DNA binding, but binding can be activated by anti-p53 monoclonal antibody. Acetylation of p300 also dramatically increases the DNA-binding activity if fixed amounts of p53. The reference does not teach a screening assay or the use of biotin to label the peptide substrate.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to package the components of Lill et al. in a kit due to the long recognized ease and convenience conferred by such an arrangement. In addition, the various reagents used to carry out an assay are often packaged together in a kit, which a skilled artisan would have known. In addition, it would have been obvious to make deacetylase a component of the kit. Since the claimed method recites selecting a compound that is associated with an increase or decrease in the amount of acetylated peptide, one would have had a reasonable expectation of success in making deacetylase a component of the kit and using it to deacetylate acetylated peptide substrates.

***Allowable Subject Matter***

11. Claims 16-22 are allowable over the prior art of record.
12. The following is a statement of reasons for the indication of allowable subject matter: the closest prior art of record fails to disclose or teach a method for screening a compound that inhibits or catalyzes acetyltransferase activity, wherein the acetyltransferase is contacted with a peptide substrate in the presence of a test compound, the amount of acetylated peptide is detected using an anti-acetylated peptide antibody, such that the antibody only binds to the acetylated form of the peptide when the antibody is at a concentration of 0.01 ug/ml or greater, and the amount of acetylated peptide is compared to a control (acetylated peptide in the absence of test compound), and the compound is selected if it is associated with an increase or decrease in acetylated peptide substrate.

Therefore, claims 16-22 are novel and unobvious over the prior art of record.

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13. Claims 16-22 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

***Response to Arguments***

14. Applicant's arguments with respect to claims 16-22 have been fully considered and are persuasive, thereby resulting in the withdrawal of the rejections over those claims. However, claims 23-24, drawn to a kit, remain rejected under 35 USC 103.

***Conclusion***

Claims 16-24 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 703-305-0509. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Kartic Padmanabhan  
Patent Examiner  
Art Unit 1641



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LONG V. LE  
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08/22/03